

# Exhibit E

## **Data: Vioxx might raise heart risk**

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### **Body**

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GAITHERSBURG, Md. -- Arthritis patients who take Vioxx because they think it's safer on the stomach should know that the blockbuster drug might increase their risk of suffering a heart attack, an FDA advisory committee concluded Thursday.

"It would be indefensible not to share this information with the public," says David Wofsy, a University of California at San Francisco rheumatologist who served as a consultant to the committee. The FDA usually follows its advisory committee's recommendations.

Merck had come before the advisory committee to make the case that Vioxx should not have to carry the same warning about gastrointestinal (GI) complications as other non-steroidal anti-inflammatory drugs, or NSAIDs. Vioxx and its rival, Celebrex, came on the market in 1999 and had two of the most successful launches of any drug, with sales totaling more than \$ 3 billion last year.

Vioxx and Celebrex had gained a reputation as "super aspirins" because they were thought to be safer on the stomach than aspirin and other NSAIDs.

Merck conducted a study of more than 8,000 patients comparing Vioxx with naproxen, sold as Aleve. The study, dubbed Vigor, found that Vioxx patients experienced significantly fewer serious ulcers than those on naproxen. On the basis of that study, the advisory committee recommended that Merck be allowed to claim only that Vioxx is safer than naproxen in patients who are not also taking low-dose aspirin to protect against heart attacks. (The Vigor study excluded patients who also were taking aspirin.)

However, Vigor also found that patients on Vioxx were more likely to suffer heart attacks and other cardiovascular complications

Data: Vioxx might raise heart risk

than those on naproxen. The advisory committee recommended that this finding be noted on Vioxx's label.

On Wednesday, the advisory committee concluded that Pharmacia, the maker of Celebrex, had failed to prove that its drug was safer on the stomach. However, Pharmacia's study included patients taking aspirin, which might have erased Celebrex's GI safety advantage. Their study also compared Celebrex to two NSAIDs, not just one as Merck had done.

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